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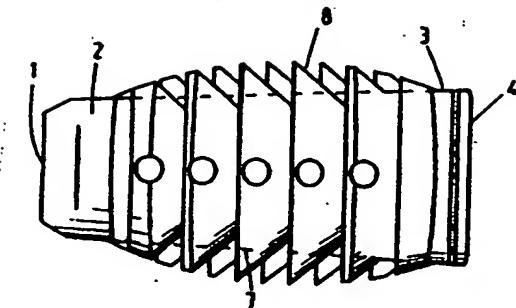
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VERTEBRAL INTERBODY FUSION PROSTHESIS

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List of Documents Cited in the Preliminary Search Report: Refer to the end of this section

[Abstract]

The prosthesis is in the shape of a cage inscribed in a surface of revolution and capable of being screwed between two vertebral end plates, and possesses for this purpose a thread, said cage also presenting at least one open central cavity (9) on opposite sides, so as to be able to receive a bone graft and enable the bony fusion with the tissue of the adjacent vertebrae and by interrupting the threads to make them self-cutting, said surface of revolution presenting a rounded shape at least on one part of its length, with preferably, a more tapered end (2).



The present invention relates to vertebral interbody fusion prostheses.

These prostheses are designed to compensate for the effects due to a trauma or degeneration of an intervertebral disk which leads to pinching or reduction in the interbody discal space causing repercussions such as, especially, compression of the nerve roots with known consequences.

In other words, the goal of these prostheses is to reestablish the appropriate discal space and generally, with the impossibility of reestablishing joint mobility with a prosthesis, to make a bony fusion of the two vertebral bodies.

A certain number of these prostheses are already known, some of which are marketed, which are presented in the shape of plugs designed to be inserted between two vertebral bodies, these plugs generally being combined in pairs and most generally put in position by the posterior route.

All these prostheses, often called interbody cages, have a certain number of characteristics which originate from the disclosure of the patent US-A-3 848 601; this patent provides for making, in both facing vertebral end plates and through the discal space, a channel with constant rectangular cross section in which is inserted a bone graft of corresponding shape. These common characteristics are the following:

cylindrical shape with constant cross section of the plug, with an anterior chamfer enabling insertion into the cylindrical channel drilled beforehand;

presence of superficial roughness or unevenness to avoid the ejection of the prosthesis;

hollow shape or comprising slits or grooves to receive a bone graft, thus giving the plug the appearance of a cage;

presence, at the posterior end, of means for temporary attachment of an ancillary tool for installation.

Such implants are especially described in the patents US-A-4 501 269 and EP-A-0 307 241.

Another type of prosthesis is based on the disclosure of the patent DE-A-3 505 567, which describes a bone implant with cylindrical shape and exhibiting a peripheral thread enabling its screwing into a space made between the two adjacent vertebrae. Such implants, also made from a resistant material, exhibit a cylindrical shape of revolution, a thread useful for ensuring the attachment by screwing and for preventing the withdrawal, slits or passages for receiving a bone graft or favoring the bone regrowth, and at one end means for temporarily receiving the end of an ancillary tool for installation by screwing. Such implants are described for example in the patent US-A-5 015 247.

Whatever may be the different designs; both types of above-mentioned implants begin with the principal that they must necessarily exhibit a constant cross-sectional surface area, extending transversally to the longitudinal axis of the spine, so as to ensure the necessary stability for optimal bone reinforcement.

The present invention proposes to provide a new prosthesis in the shape of cages to be plugged, especially in the form of a plurality of cages, preferably two cages, for vertebral interbody fusion, making it possible to improve the synthesis and bone reinforcement.

Another objective of the invention is to provide such a prosthesis exhibiting increased stability minimizing the risks of expulsion or displacement of the prosthesis.

Yet another objective of the invention is to produce such a prosthesis in the shape of cages very easy to implant and to remove.

The subject of the invention is a vertebral interbody fusion prosthesis being presented in the shape of a cage or plug inscribed in a surface of revolution and capable of being screwed between two vertebral end plates facing each other by penetrating the bone substance and possessing, for this purpose, a thread, said cage also exhibiting at least one open central cavity on opposite sides, so as to be able to receive a bone graft and enable the bony fusion with the tissue of adjacent vertebrae and to interrupt the threads to make them self-cutting, characterized in that said surface of revolution exhibits a rounded shape on at least one part of its length.

In this way, at least one of the ends of the prosthesis and especially the anterior end has relatively tapered shape.

In the particularly preferred embodiment, the anterior part of the rounded cage has a diameter less than that of the posterior part, such that the rounded surface extends from an underlying truncated geometric surface. This arrangement also has the advantage of facilitating the restoration of normal lumbar lordosis.

The angle at the top of such a truncated cone is preferably between 3 and 7°, and especially 5°.

If applicable, the anterior and/or posterior ends of the cage-plug may not be rounded, by being formed from a generatrix, preferably rectilinear, which then forms an anterior and/or posterior end conical in shape.

The radius of curvature of the rounded surface is preferably between 20 and 35 mm, and, especially on the order of 25 mm.

The center of curvature is preferably spread laterally from the axis of revolution of the cage with a distance on the order of 19 to 22 mm, according to the size of the implant.

Preferably, the cage of the prosthesis according to the invention exhibits a single thread, the pitch of which enables easy screwing between the two adjacent vertebral bodies. Preferably, the threads, may be triangular and may or may not symmetrical.

The depth of the threads may be constant, such that the bottoms of the threads are found on a rounded geometric surface parallel to the rounded surface coinciding with the tops of the threads. However, it is preferred for the depth of the threads to be variable, so that their bottoms are found on a geometric surface parallel to said surface, preferably truncated and moved towards the axis of revolution of the cage.

Preferably, the depth of the threads is between 1 and 3 mm, and especially, on average, 2 mm.

The pitch of the thread is preferably between 1 and 3 mm.

The hollow central part, or cavity, of a cage opens by diametrically opposite openings extending, preferably, on a substantial length of the cage, such that the intersection line between the surface of revolution in which the cage is inscribed and the surface creating the central cavity is a line remaining rounded.

Preferably, this cavity leads to longitudinal grooves extending the entire length of the cage, where all the threads are then self-cutting.

In addition, holes or transverse openings may be provided that connect the central cavity and the lateral surfaces, to enable lateral bone diffusion.

Conventionally, the cage according to the invention may include, preferably at its posterior end, means for temporarily receiving a tool for installation and screwing.

The prosthesis cage according to the invention may be produced from any material usually used for implants of this type, for example from metal or synthetic material, preferably radiotransparent. The surface may be treated, for example with roughness fines or even be covered with a material facilitating the bone growth, for example calcium hydroxyapatite.

In fact, due to a coating of this biomaterial on the external surface of the cup it becomes possible, after having made primary attachment through the mechanical effect of the screws, to carry out a "secondary" attachment, physiochemical in nature, which reinforces the first attachment in the first months following the operation. This attachment is obtained by adsorption

of the different components of the bony tissue on the deposit of calcium hydroxyapatite covering the external surface of the cup.

In this way, an attachment at two times is carried out, first mechanical by the threads, the shape of the cage and the roughness of the coating of hydroxyapatite, then physicochemical by adsorption of bone components on the hydroxyapatite several months later.

For installation of the prosthesis, the surgeon, after having cut his approach route, preferably posterior, and in this case moved the corresponding segment of the CNS laterally, presents the cage in plug form by its anterior end into the intervertebral space, and then begins by screwing the cage in a sagittal plane through the intervertebral space. The thread rapidly bites into the cortical bones of the vertebral end plates which are facing each other and progressively the passage of the tapered anterior end of the cage causes a spreading apart of the vertebral end plates while the cage advances by coming, with its thread points, in contact with the spongy bone of the vertebral bodies through the cortical bone. Once the cage is positioned, its rounded shape at the level of its upper and lower parts, respectively, is approximately adapted to the clearly concave shapes of the end plate of the upper vertebra and slightly concave shapes of the lower vertebra, which facilitates the distribution of the forces and ensures good stability. Also, better development of the bone tissue and good cooperation with the bone grafts introduced beforehand into the hollowed central part of the cage are obtained, leading to good fusion. Moreover, accidental withdrawal of the cage is considerably reduced, because the central bulge of the cage opposes its extraction.

Finally, in contrast to the fears expressed in the prior art, which have led to looking for systematically cylindrical shapes to avoid the risks of movement from bending of the spine on both sides of the implanted plug, excellent stability is obtained from the junction at the level of the implanted plug including when one seeks to reduce lordosis.

Other advantages and characteristics of the invention will appear with reading the following description, made by way of nonlimiting example by referring to the attached drawing in which:

Figure 1 represents a view in perspective of a prosthesis cage according to the invention;

Figure 2 represents a front view of the cage;

Figure 3 represents a top view of the cage;

Figure 4 represents a view in front of the cage;

Figure 5 represents a view in back of the cage.

The cage represented in the drawing is made for example from titanium, but it may sometimes be made from any other biocompatible material with suitable resistance. It exhibits a shape of a peg or a rounded cage inscribed in a surface of revolution in the shape of an elongated keg. The frontal surface 1 of the anterior end 2 of the cage is flat, and from the end the diameter

of the cage increases progressively, conferring on the anterior part of the cage a tapered look. The diameter becomes maximum in the central part of the cage then returns to decreasing in the direction of the back end 3, in the frontal surface 4 of which is made a cavity designed to receive the end of a screwing tool with a recessed hole 5 and a diametral groove 6. The shapes of this hole and this groove are conventional and have not been described further.

In the example represented, it is seen especially in Figure 2 that the anterior 2 and posterior 3 ends are situated on a geometric truncated cone, that is, imaginary, 7, represented in broken line, such that the rounded part extends radically [sic; radially] towards the exterior from this underlying surface 7. Moreover, it is understood that towards the back end 3, the rounded part is less tapered than towards the front end 2, the rounded part is less tapered than towards the front end 2. The angle of the top of this geometrical cone is on the order of 5° in this example.

Moreover, it is seen that the anterior 2 and posterior 3 ends are conical and exterior to the rounded part of the cage, but it is understood that in another embodiment, the rounded shape may be extended up to the front 1 and/or back 4 frontal surfaces.

On practically its entire length the cage presents a thread 8, with a pitch preferably on the order of 2 mm and threads with progressively increasing diameter from the end towards the center, these threads having a triangular cross section with a surface inclined towards the front and towards the center and a back surface situated approximately in a diametral plane.

It is seen in Figure 2 that the bottoms of the threads may advantageously be arranged on a truncated cone surface parallel to surface 7, and moved relative to the latter towards the longitudinal axis of revolution of the cage.

In the central part of the cage, a diametral cavity 9 is made that is created by an oblong cylindrical surface, the generatrix of which is seen clearly in Figure 3. This cavity, which crosses right through the cage, cuts the rounded surface in the shape of a keg, in which the cage is inscribed, according to a line advantageously curved inward.

The central oblong cavity 9 opens at each of its ends in a groove 10, the transverse section of which is clearly seen in Figures 4 and 5. These grooves delimit slots 11,12 in the front and back of the prosthesis. They interrupt the threads of the thread 8 which thus becomes self-cutting. In the example described, the bottom of each groove made by areas 11,12 is flat, but this bottom may be any other shape.

Also, there may not be any grooves provided, such that only the threads intersected by the cavity 9 would remain self-cutting.

Advantageously, transverse diametral holes 13 may cross right through the cage in directions perpendicular to the wall of the central cavity 9, thus enabling a transverse bone progression once the cavity 9 has been brought to its final sagittal position by rotation of the implant.

Now it is understood that the cage exhibits a shape that is anatomically near to that of a normal disk, viewed silhouetted in the vertical sagittal plane.

Although the invention has been described with the aid of a particular embodiment, it is clearly understood that it is in no way limited and that various modifications in shapes or materials may be brought to it.

Claims

1. Vertebral interbody fusion prosthesis in the shape of a cage inscribed in a surface of revolution and capable of being screwed between two vertebral end plates facing each other while penetrating the bone substance and possessing thread (8) for this purpose, said cage also exhibiting at least one open central cavity (9) on opposite sides so as to be able to receive a bone graft and enable the bony fusion with the tissue of the adjacent vertebrae, and by interrupting the threads to make them self-cutting, characterized in that said surface of revolution exhibits a rounded shape at least on one part of its length.

2. Prosthesis according to Claim 1 characterized in that one of the ends has a tapered shape.

3. Prosthesis according to Claim 2 characterized in that the anterior part (1) of the rounded cage has a diameter less than that of the posterior part (2), such that said rounded surface extends from an underlying truncated geometric surface (7).

4. Prosthesis according to Claim 3 characterized in that the angle of the top of said conical surface (7) is between 3 and 7 and especially on the order of 5°.

5. Prosthesis according to one of Claims 1 to 4 characterized in that the radius of curvature of said rounded surface is between 20 and 35 mm, and especially on the order of 25 mm.

6. Prosthesis according to one of Claims 1 to 5 characterized in that the center of curvature is moved from the geometric axis of the cage by a distance of 19 to 22 mm.

7. Prosthesis according to one of Claims 2 to 6 characterized in that the anterior (2) and/or posterior (3) ends of the cage are not rounded.

8. Prosthesis according to Claim 7 characterized in that said ends are truncated and aligned on said truncated surface (7).

9. Prosthesis according to one of Claims 1 to 8 characterized in that the cage of the prosthesis exhibits a single thread (8), the pitch of which enables easy screwing between the two adjacent vertebral bodies.

10. Prosthesis according to one of Claims 1 to 9 characterized in that the depth of the threads is between 1 and 3 mm and especially 2 mm.

11. Prosthesis according to one of Claims 1 to 10 characterized in that the pitch of the thread (8) is between 1 and 3 mm.

12. Prosthesis according to Claim 10 characterized in that the depth of the threads is variable and that the bottoms of the threads is found on the truncated surface, coinciding with or centrally moved forward from said truncated geometric surface (7).

13. Prosthesis according to one of Claims 1 to 12 characterized in that the hollow central part or cavity (9) of a cage opens by diametrically opposite openings extending along a substantial length of the cage.

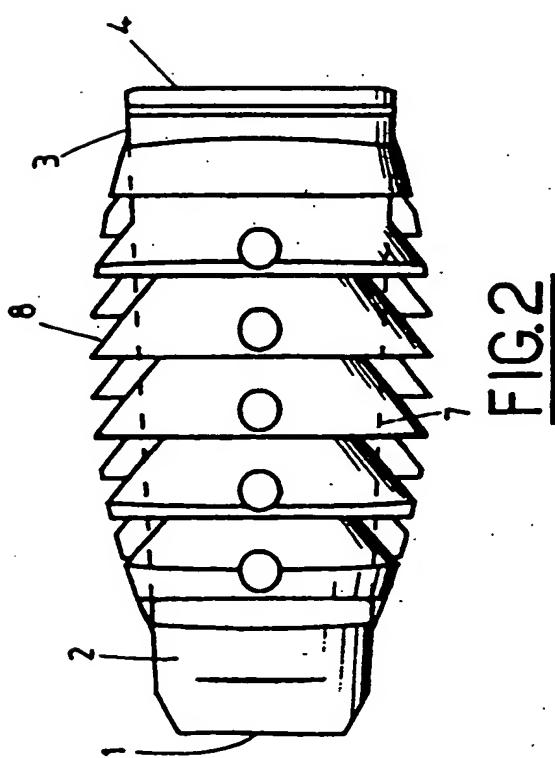
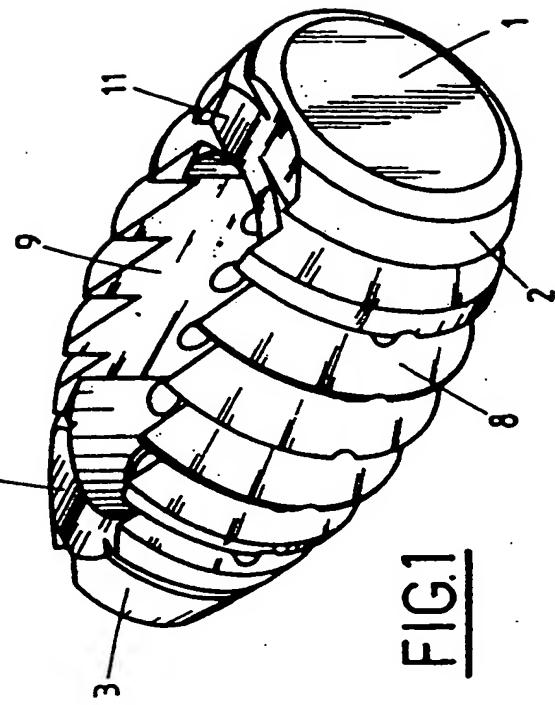
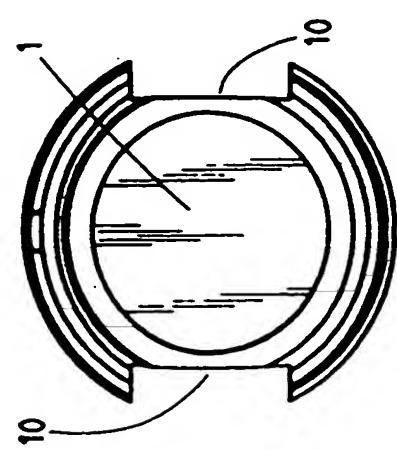
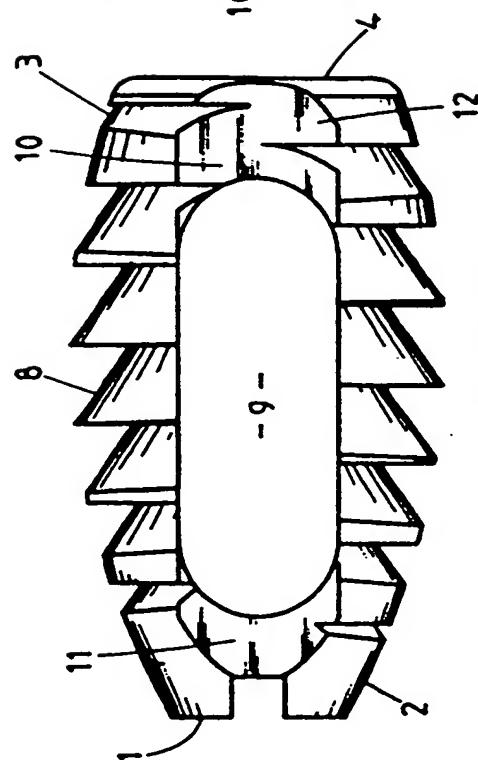
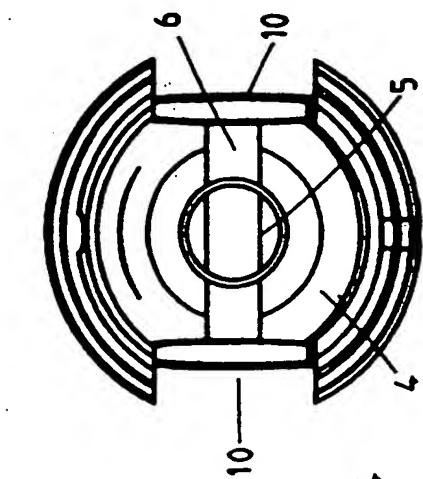
14. Prosthesis according to Claim 13 characterized in that this cavity (9) leads to longitudinal grooves (10) extending the entire length of the cage, in which all the threads are then self-cutting.

15. Prosthesis according to one of Claims 1 to 14 characterized in that the cage includes transverse holes (13) communicating with said central cavity (9) for a transverse progression of the bone growth.

16. Prosthesis according to one of Claims 1 to 15 characterized in that its surface is rough and/or covered with a coating of calcium hydroxyapatite.

17. Prosthesis according to any one of Claims 1 to 16 characterized in that the cage includes at its posterior end means (5,6) for temporarily receiving a tool for installation and screwing.

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FA 521916
FR 9514655

SEARCH REPORT
established on the basis of the most
recent claims filed before the start
of the search

| DOCUMENTS CONSIDERED TO BE RELEVANT | | Claims concerned in the examined document |
|--|--|---|
| Category | Citation of document with indication where appropriate, of relevant passages | |
| Y | DE-A-43 02 397 (ASAHI KOGAKU KOGYO) *Claims; Figures 11, 14, 17* | 1-6, 9, 13, 15-17 |
| Y | EP-A-0 637 440 (ADVANCED TECHNICAL FABRICATION) *Column 3, line 50 – line 57; Claims 1, 3, 10, 11; Figure 5* | 1-6, 9, 13, 15-17 |
| A | FR-A-2 710 519 (ROBINE) *Abstract; Figures 1, 2* | 1, 13, 15, 17 |
| A | WO-A-95 25487 (PISHARODI) *The entire document* | 1-3, 17 |
| D,A | US-A-5 015 247 (MICHELSON) *The entire document* | 1, 9, 14, 15, 17 |
| A | WO-A-95 08306 (SYNTHES) | |
| A | WO-A-95 08964 (BRANTIGAN) | |
| D,A | EP-A-0 307 241 (BRANTIGAN) | |
| Date of completion of the search | | Examiner |
| July 22, 1996 | | C. Klein |
| CATEGORY OF CITED DOCUMENTS | | |
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